

Remarks

Claims 1-21, 24, 27, 28, and 30-37 are pending. Claims 1-21, 24, 27, 28, 30-33, and 37 are allowed.

Applicants thank the Examiner for the telephonic interview with the undersigned on May 22, 2006, wherein the patentability of claims 34-36 was discussed. It was agreed that these claims should be allowed for the reasons set forth in the last response (the same reasons claim 1 has been allowed), but that Applicants should submit a written response more clearly pointing out the distinguishing features of the device of claim 34 vis-à-vis the cited prior art.

Rejections Under 35 U.S.C. § 103

Claims 34 and 35 were rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,797,898 to Santini Jr. et al. (hereinafter “Santini”) in view of Rubin et al., “The Potential of Parathyroid Hormone as a Therapy for Osteoporosis,” *Int. J. Fertil.* 47(3):103-15 (2002) (hereinafter “Rubin”). Claim 36 was rejected under 35 U.S.C. § 103(a) as obvious over Santini and Rubin, further in view of U.S. Patent No. 6,264,990 to Knepp et al. (hereinafter “Knepp”) and U.S. Patent No. 6,011,011 to Hageman (hereinafter “Hageman”). The rejections are respectfully traversed.

The Device of Applicants’ Claim 34

The devices of claims 34-36 require an electrically conductive reservoir cap covering each reservoir, *conducting leads to and from each reservoir cap*, and a power source and a controller for selectively delivering an *electric current through the reservoir cap* effective to rupture the reservoir cap. This is a structure specifically for reservoir activation, i.e., reservoir opening, by electrothermal ablation.

Santini

Santini describes, for example, active disintegration of reservoir caps by an electro-*chemical* mechanism, wherein an electric voltage is established between an anodic reservoir cap and a separate cathode through a conductive fluid in contact with the anode and cathode. Application of the voltage causes the anode to oxidize, and the oxidized material dissolves into the conductive fluid, thereby disintegrating the reservoir cap. That process is an entirely distinct mechanism of action compared to electrothermal ablation.

Moreover, Santini does not disclose the structure recited in Applicants' claim 34. In particular, Santini does not teach a device having conducting leads connected to and from a reservoir cap. In Santini's device, there is only a *single* lead to the anodic reservoir cap. The cathode is not connected to the anode by any conducting lead. Rather, a complete, operable electrical circuit is possible only when the cathode and the anode are in contact with an electrolytic fluid. Santini simply does not disclose or remotely suggest the electrothermal ablation technique or structures therefor.

Rubin, Knepp, and Hageman

Rubin fails to remotely suggest a device that has utilizes electrothermal ablation to disintegrate reservoir caps to initiate release of PTH, as required by Applicants' claims 34-36.

Furthermore, one skilled in the art would not have been motivated to combine the teachings of Santini and Rubin in light of Rubin's teaching away from the use of an implantable medical device for administration of PTH.

Knepp discloses stable, non-aqueous protein formulations. Hageman discloses protein formulations that include polyethylene glycol as an excipient. Nothing in Knepp or Hageman

U.S.S.N. 10/654,761
Filed: September 4, 2003
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supplements the deficiencies of the teachings of Santini and Rubin. For instance, nothing in Knepp or Hageman remotely teaches *electrothermal ablation* of a reservoir cap to initiate release of parathyroid hormone from a reservoir.

Conclusions

In view of the foregoing remarks, Applicants respectfully submit that the claims are non-obvious over the prior art of record. All claims are believed to be in condition for allowance. Prompt allowance of each of the pending claims is therefore respectfully solicited.

The undersigned kindly invites the Examiner to contact him by telephone (404.853.8068) if any outstanding issues can be resolved by conference or examiner's amendment.

Respectfully submitted,



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Date: June 6, 2006

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